

## REMARKS

Support for new claim 25 can be found on page 4, lines 26-33 of the specification.

Support for new claim 26 can be found on page 4, lines 29-30 of the specification.

### Objection to the Declaration

The Applicants note the Examiner's comments with regard to the allegedly defective Declaration. A substitute Declaration is currently being prepared and will be submitted for consideration in due course.

### Rejections under 35 U.S.C. 112, second paragraph

The rejection of claims 14-16, 18-20, and 22 under 35 U.S.C. 112, second paragraph, is respectfully traversed. Applicants have asserted that one skilled in this art area understand the term "mobilization" to refer to the circulatory system following physical, environmental, or other, factors impacting on the immune system. A discussion of cell mobilization can be found in the attached copy of U.S. Patent No. 6,875,753 at col.2, line 39, to col. 3, line 5.

In view of the above remarks, Applicants submit that the present claims are clear and concise to a person of ordinary skill in the art. Accordingly, withdrawal of the rejection under 35 U.S.C. 112, second paragraph, is respectfully urged.

### Rejections under 35 U.S.C. 112, first paragraph

The rejection of claims 14-16, 19, 20, and 22 under 35 U.S.C. 112, first paragraph, is respectfully traversed:

The Patent Office has taken the position that the rejection under 35 U.S.C. 112, first paragraph, is not a rejection for lack of enablement, but for a lack of adequate written

description for the genus of “interleukins that block differentiation towards the macrophage pathway” of claims 14, 16, and 20, and the genus of “cell growth factors” of claim 19.

Section 112 of the Patent Act states:

“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”

The patent application is addressed to one who is skilled in the art to which the invention pertains. The application, therefore, need not contain disclosure of what is already known to those skilled in the art. In fact, such information need not be included.

One portion of the written description requirement is that the invention contains a description of the “best mode” of practicing the invention known to the inventor(s) at the time of filing the application. The best mode of carrying out the present invention is not in question, nor should it be.

Another part of the written description requirement is that an “enabling disclosure” must be provided. This requires that one skilled in the art or science to which the invention relates would be enabled from the disclosure to practice the invention without having to engage in “undue experimentation.” The mere fact that some experimentation is required does not mean that disclosure fails to satisfy the enabling requirement.

Applicants respectfully submit that the specification is enabling for the terms “an interleukin that blocks differentiation towards the macrophagic pathway” and “cell growth factor”.

The Applicants have disclosed that interleukin-4 and interleukin-13 are examples of interleukins that can be used in the invention (page 3, lines 14-20).

The Applicants have also provided examples of cell growth factors, namely granulocyte colony stimulating factor (G-CSF) and granulocyte-macrophage colony stimulating factor (GM-CSF) on page 4, lines 28-33, of the specification.

It is respectfully submitted that such information would provide guidance to those of ordinary skill in the art to enable them to practice the claimed invention without undue experimentation.

Moreover, the burden is on the Patent Office to provide reasons and/or examples in support of their belief that the presumptively enabling disclosure does not support the claimed invention.

As both the best mode and enablement requirements have been met in this application, the rejection under 35 U.S.C. 112, first paragraph, is unsustainable and should be withdrawn.

Rejections under 35 U.S.C. 103(a)

The rejection of claims 14-16, 19, 20, and 22 under 35 U.S.C §103 (a) as being unpatentable over the Tarte et al. reference in *Blood*, 91: 1852-1857 (1980) in view of Ponting (US 5,405,772) is respectfully traversed.

Preliminarily, Applicants wish to state for the record that they have nowhere made an admission that the presently claimed invention is obvious in view of the prior art, contrary to the implication made by the Patent Office on page 4, last paragraph, of the February 10, 2006, Office action.

The arguments made by Applicants in their response filed on December 1, 2005, that the present invention is not obvious over a combination of Tarte et al. and Ponting, are reiterated herein.

Furthermore, with regard to the date submitted in Tables A and B, Applicants will provide a Declaration under 37 C.F.R. 1.132 in due course.

The rejection of claim 18 under 35 U.S.C §103 (a) as being unpatentable over Tarte et al. in view of Ponting and further in view of Kalinski et al. is respectfully traversed.

The arguments made by Applicants in their response filed on December 1, 2005, that the invention of claim 18 is not obvious over a combination of Tarte et al., Ponting, and Kalinski et al. are reiterated herein.

The Patent Office still has not provided any evidence or reasoning as to why a person of ordinary skill in the art would have found it obvious that that in a serum-free medium, the PGE<sub>2</sub> would have the indicated action, as explained on pages 6 and 7 of the specification.

Favorable action is solicited.

**Applicants hereby petition the Commissioner for Patents to extend the time for reply to the Office action mailed on February 10, 2006, for three (3) months from May 10, 2006, to August 10, 2006. A duly completed credit card authorization form is attached to effect payment of the extension fee.**

Respectfully submitted,



Malcolm J. MacDonald

Reg. No. 40,250

Tel: (703) 837-9600 Ex. 24

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